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APPLICATION NO.	FILING DATE		FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,368	08/06/2003		Kenneth Stewart	STEWART	6917
75	7590 05/16/2006			EXAMINER	
Evelyn M. Soi	mmer		KIM, JOHN		
Suite 825					
250 Park Avenu	ie		ART UNIT	PAPER NUMBER	
New York, NY 10022				3733	
				DATE MAILED: 05/16/2006	5

Please find below and/or attached an Office communication concerning this application or proceeding.

	•	<i>_</i>					
	Application No.	Applicant(s)					
	10/634,368	STEWART, KENNETH					
Office Action Summary	Examiner	Art Unit					
	John Kim	3733					
The MAILING DATE of this communication ap Period for Reply	pears on the cover sheet with the	correspondence address					
A SHORTENED STATUTORY PERIOD FOR REPL WHICHEVER IS LONGER, FROM THE MAILING E  - Extensions of time may be available under the provisions of 37 CFR 1. after SIX (6) MONTHS from the mailing date of this communication.  - If NO period for reply is specified above, the maximum statutory period - Failure to reply within the set or extended period for reply will, by statut Any reply received by the Office later than three months after the mailine earned patent term adjustment. See 37 CFR 1.704(b).	DATE OF THIS COMMUNICATIO .136(a). In no event, however, may a reply be d will apply and will expire SIX (6) MONTHS fro te, cause the application to become ABANDON	ON. timely filed om the mailing date of this communication. NED (35 U.S.C. § 133).					
Status							
1) Responsive to communication(s) filed on	<u></u> .						
2a) This action is <b>FINAL</b> . 2b) ⊠ Thi	This action is <b>FINAL</b> . 2b)⊠ This action is non-final.						
•	Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under	closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.						
Disposition of Claims							
4) Claim(s) 1-20 is/are pending in the application.							
4a) Of the above claim(s) 2-5 and 13-20 is/are	4a) Of the above claim(s) 2-5 and 13-20 is/are withdrawn from consideration.						
5) Claim(s) is/are allowed.							
6)⊠ Claim(s) <u>1 and 6-12</u> is/are rejected.	i)⊠ Claim(s) <u>1 and 6-12</u> is/are rejected.						
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/	or election requirement.						
Application Papers							
9)☐ The specification is objected to by the Examin	er.						
10)⊠ The drawing(s) filed on <u>06 August 2003</u> is/are: a) accepted or b)⊠ objected to by the Examiner.							
Applicant may not request that any objection to the	e drawing(s) be held in abeyance. S	ee 37 CFR 1.85(a).					
Replacement drawing sheet(s) including the corre	· · · · · · · · · · · · · · · · · · ·	·					
11)⊠ The oath or declaration is objected to by the E	Examiner. Note the attached Office	ce Action or form PTO-152.					
Priority under 35 U.S.C. § 119							
12)  Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).  * See the attached detailed Office action for a list of the certified copies not received.							
- See the attached detailed Oπice action for a ils	t of the certified copies not recei	vea.					
Attachment(s)							
1) Notice of References Cited (PTO-892)	4) Interview Summa						
<ul> <li>2) Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)</li> </ul>	Paper No(s)/Mail 8) 5) Notice of Informa	Date Il Patent Application (PTO-152)					
Paper No(s)/Mail Date	6) Other:						

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### **DETAILED ACTION**

#### Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-15, drawn to a cover or shield, classified in class 606, subclass

54.

II. Claims 16-20, drawn to a method, classified in class 606, subclass 86.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the method of preventing ingrowth can be performed by a another different apparatus.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species:

- a) Figure 1
- b) Figure 2
- c) Figure 3a and 3b
- d) Figure 4
- e) Figure 5

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims appear to be generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.

MPEP § 809.02(a).

During a telephone conversation with Ms. Evelyn Sommer on 5/10/06 a provisional election was made without traverse to prosecute the invention of I, species d (figure 4), claims 1, 4, 6-13, 15. Affirmation of this election must be made by applicant in replying to this Office action. Claims 2, 3, 5, 14, and16-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is further noted the elected invention/species does not have the limitations of claims 4 (figure 1), 13 (figure 5), and 15 (figure 5). Thus claims 4, 13, and 15 are withdrawn from consideration. See MPEP 821.

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The pending claims are 1 and 6-12.

#### Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

The specification to which the oath or declaration is directed has not been adequately identified. See MPEP § 602.

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

It does not state that the person making the oath or declaration believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.

## **Drawings**

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the limitation of "a lower cinch ring having openings" must be CLEARLY shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure

is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

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It is further noted the drawings are informal and applicant is encouraged to replace all the drawings with better drafting.

#### Claim Objections

Applicant is requested to recite the limitations properly and fully to avoid confusion. The pronoun "it" or "its" is indefinite and confusing. It is noted that below is some of the examples seen in the claims. Applicant is requested to thoroughly search for objectionable language and correct as required.

Claim 1 is objected to because of the following informalities: the limitation "cap or casing" should recite "a hollow cap or casing pouch" to avoid confusion. Appropriate correction is required.

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Claim 12 is objected to because of the following informalities: the limitation "cinch ring" should recite "lower cinch ring" to avoid confusion. Appropriate correction is required.

Claim 12 is objected to because of the following informalities: "it" is recited in the claim. For examining purpose, "it" will be replaced with cover or shield. Appropriate correction is required.

## Claim Rejections - 35 USC § 112

Claims 1, 6, 9, and 11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The applicant is reminded when reciting a new limitation into the claims, the limitation begins with the words "a" or "an," and all subsequent recitations of the limitation should be begin with the words "the" or "said."

Claim 1 recites the limitation "projecting parts" and "instrumentation" in line 3.

There is insufficient antecedent basis for this limitation in the claim.

Claim 6 recites the limitation "the fastener portion" and "sutures" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 9 recites the limitation "one or more drawstrings" and "pouch opening" in line 2-3. There is insufficient antecedent basis for this limitation in the claim.

Claim 11 recites the limitation "openings" and "suture strings" in line 2 and 3.

There is insufficient antecedent basis for this limitation in the claim.

# Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 6-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Bohan et al. (US Pat 5279539).

In regards to claims 1 and 9, Bohan discloses a hollow cap or casing portion (11) and a fastener portion or a drawstring (31) provided at a lower portion of the cap or casing. (figure 7). It is noted Bohan's device is disclosed for enclosing an internal bodily organ or tissue (abstract), and thus is dimensioned to be placed over bone instrumentation. In regards to claim 6, Bohan discloses the fastener portion includes sutures (31) which can be used for attaching to the bone instruments (34). In regards to claim 7, Bohan discloses having a lower frame (30) which can provide an open, box – like aperture since it is has wire-like properties (col 6:21-26). In regards to claims 8 and 10, Bohan discloses having a cap or casing made of flexible pouch or sheath (fabric material, col 5:41-45). In regards to claims 11 and 12, Bohan discloses having a lower cinch ring (21) with openings (see figure 6 where the drawstrings enter the pouch) (col 5: 23-40). It is noted that another hemline can be added to bring the cap down vertically.

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It is acknowledged that functional language is as important as the structural limitations. However, while features of an apparatus may be recited either structurally or functionally, claims directed to an apparatus must be distinguished from the prior art in terms of structure rather than function. (See MPEP 2114). If the functional language is silent in the prior art, then the examiner will determine if the prior art can inherently perform the claimed function. To establish inherency, extrinsic evidence must be presented. In this case, the extrinsic evidence is the structural similarity to the disclosed invention (*In re Schreiber*, 128 F.3d.1473, 44 USPQ2d 1429 (Fed Cir 1997)).

#### Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. See PTO-892 for art cited of interest.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John Kim whose telephone number is (571) 272-2817. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

JK 🗇

EDUARDO C. ROBERT SUPERVISORY PATENT EXAMINER